

## REMARKS

### **I. Status of the Claims**

Claims 75, 76, 78, 80, 82, 83, 88-106, and 108-112 were pending at the time the Office Action dated September 9, 2009 ("the Action"), was mailed. Claims 75, 78, and 82 are amended herein, as described below. No new matter is added by these amendments. Claim 90 is canceled. Claims 75, 76, 78, 80, 82, 83, 88, 89, 91-106, and 108-112 are therefore pending.

### **II. The Enablement Rejection Is Overcome**

Claims 75, 76, 78, 80, 82, 83, 88-106,<sup>1</sup> and 108-112 remain rejected under 35 U.S.C. § 112, first paragraph, as failing the enablement requirement. In responding to applicants' previous arguments, the Examiner contends that out of Examples 1-1094 described in the application, Y ≠ S. It is asserted that this observation contributes to the alleged unpredictability of the activities of the claimed compounds, wherein such unpredictability renders the claim not enabled.

Applicants respectfully disagree. The Examiner has the initial burden of producing reasons that substantiate a rejection based on lack of enablement. *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971); *see also* M.P.E.P. § 2164.02. This burden requires a factual basis or scientific principle to reasonably doubt the accuracy of a clear disclosure to be supplied. *In re Marzocchi*, 439 F.2d at 224. The Action, however, fails to provide a factual basis or scientific principle to reasonably doubt the accuracy of the present disclosure. In particular, the Examiner provides no evidence to show that substituting sulfur for oxygen in the manner suggested affects activity such that a sulfur-containing compound is not enabled. Indeed, even more broadly, the Examiner provided no evidence that substitution of sulfur for oxygen generally results in an

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<sup>1</sup> Although the Action lists Claim 87 as included in this rejection, applicants assume this canceled claim was not intended to be rejected.

activity change as between any two compounds such that the sulfur-containing compound's activity is altered in a way that would suggest a similar substitution in the claimed compounds would render a sulfur-containing compound not enabled. For at least this reason, a *prima facie* case of non-enablement has not been shown and the rejection is not proper.

However, in an effort to advance prosecution in this case and secure prompt allowance, and without prejudice toward applicants' right to pursue the cancelled subject matter in this or any application that claims priority to this application, the claims have been amended to delete the option wherein  $Y = S$ . Applicants assert that the amended claims are enabled for at least the reasons set forth in applicants' previous response filed July 30, 2009, incorporated herein.

Applicants also wish to re-assert that structural variation among the claimed compounds is not fatal to enablement. The Examiner appears to again contend that simply because variation in activity may exist among members of the claimed genus, such variation is to be equated with a degree of unpredictability that renders the claims not enabled. *See, e.g.*, Action, page 10. This is not the law. Breadth of structural diversity does not necessarily equal unpredictability, and the Examiner has failed to provide acceptable evidence or reasoning to support the contention that such diversity corresponds to unpredictability with respect to the claimed methods. *See Ex parte Cho*, Appeal No. 2001-2646 at page 9 (Bd. Pat. App. & Interf. 2003), *citing In re Marzocchi*, 439 F.2d at 224. As emphasized on page 8 of *Cho* in the context of an accusation regarding allegedly over-broad claims in that case, an "examiner must do more than point to a lack of evidence supporting the breadth of the claims. The burden is not on the applicants to show that the disclosure in the specification is correct; the burden is on the examiner to show that it is not." Here, the Examiner has failed to provide acceptable evidence or reasoning as to how activity differences among the compounds reasonably and necessarily correspond to non-enabling unpredictability with respect to the claimed methods. "Pointing out a lack of independent

evidentiary support is not enough" to carry the burden of establishing a *prima facie* case of non-enablement. *Id.* at page 9.

As discussed in applicants' previous response, the specification teaches that a Raf inhibitor is a compound that exhibits an IC<sub>50</sub> with respect to Raf kinase activity of no more than about 100 µM, and more typically not more than about 50 µM. Specification, page 10, lines 6-8. Although the level of Raf kinase inhibitory activity may vary from compound to compound, the specific level is irrelevant, provided the level of inhibitory activity is no more than about 100 µM. Not only are all of the tested compounds in the present disclosure Raf inhibitors, but all of the compounds tested demonstrated activity well within the scope of this defined term. Applicants submit that this evidence counters any assertion that the claims suffer from non-enabling unpredictability.

For the foregoing reasons, as well as those presented in applicants' previous response, the claims comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.

#### **IV. The Provisional Double Patenting Rejection**

Claims 75, 76, 78, 80, 82, 83, 88-106, and 108-112 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting over co-pending Application No. 12/315,779. In view of the arguments presented above, the provisional obviousness-type double patenting rejection is the only remaining rejection in the present case. Further, applicants note that the '779 application, filed after the present application, has not issued at this time and a non-final Office Action has issued in that case. "If a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a


patent without a terminal disclaimer." M.P.E.P. § 804. In view of this guidance provided by the M.P.E.P., and without conceding that double patenting exists as between the present application and the '779 application, applicants respectfully request the withdrawal of the provisional double patenting rejection such that the present case may proceed to allowance. If circumstances change, however, it is applicants' intention to file a Terminal Disclaimer, if necessary.

#### CONCLUSION

In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance, and a Notice of Allowance is requested. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1649.

Respectfully submitted,

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